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(54) **VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE AND METHOD OF VENTILATING A PATIENT USING THE SAME**

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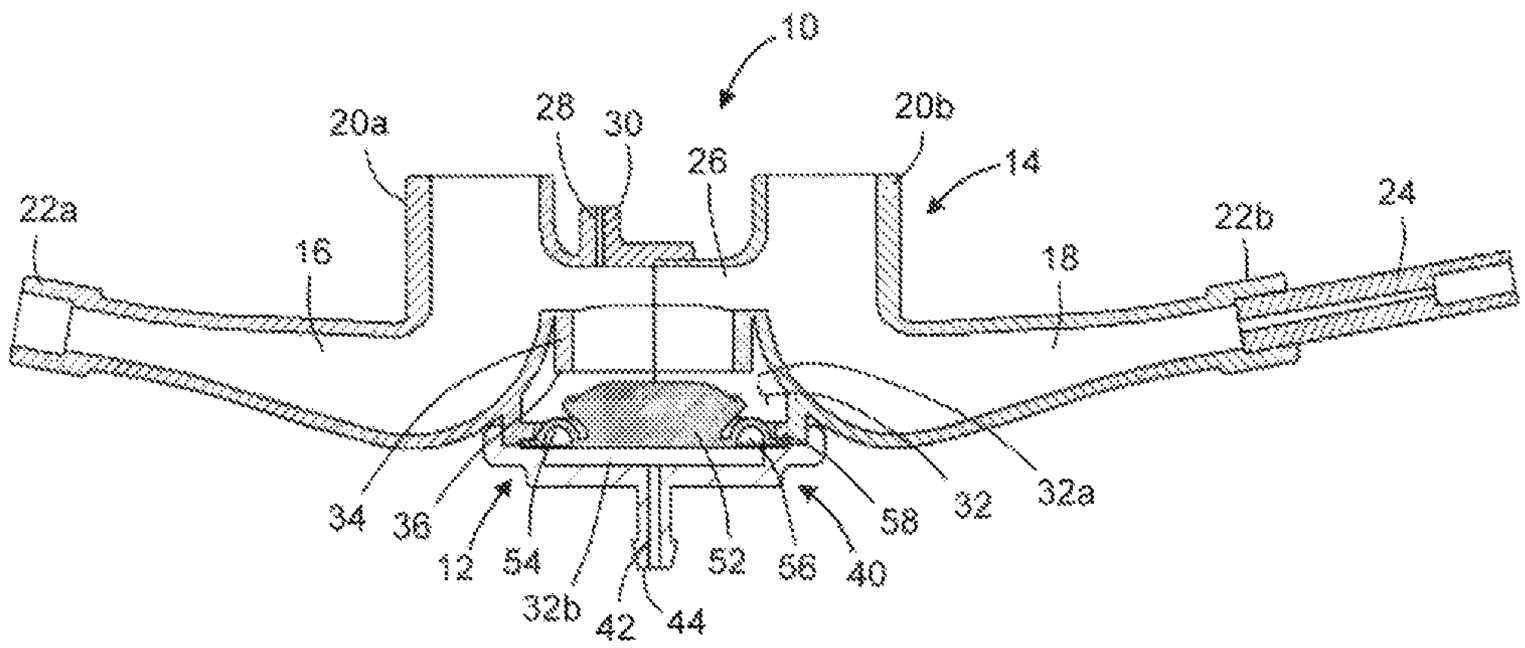
(57) **ABSTRACT**

In accordance with the present invention, there is provided a mask for achieving positive pressure mechanical ventilation (inclusive of CPAP, ventilator support, critical care ventilation, emergency applications), and a method for a operating a ventilation system including such mask. The mask of the present invention includes a piloted exhalation valve that is used to achieve the target pressures/flows to the patient. The pilot for the valve may be pneumatic and driven from the gas supply tubing from the ventilator. The pilot may also be a preset pressure derived in the mask, a separate pneumatic line from the ventilator, or an electro-mechanical control. Additionally, the valve can be implemented with a diaphragm or with a flapper.

16 Claims, 4 Drawing Sheets



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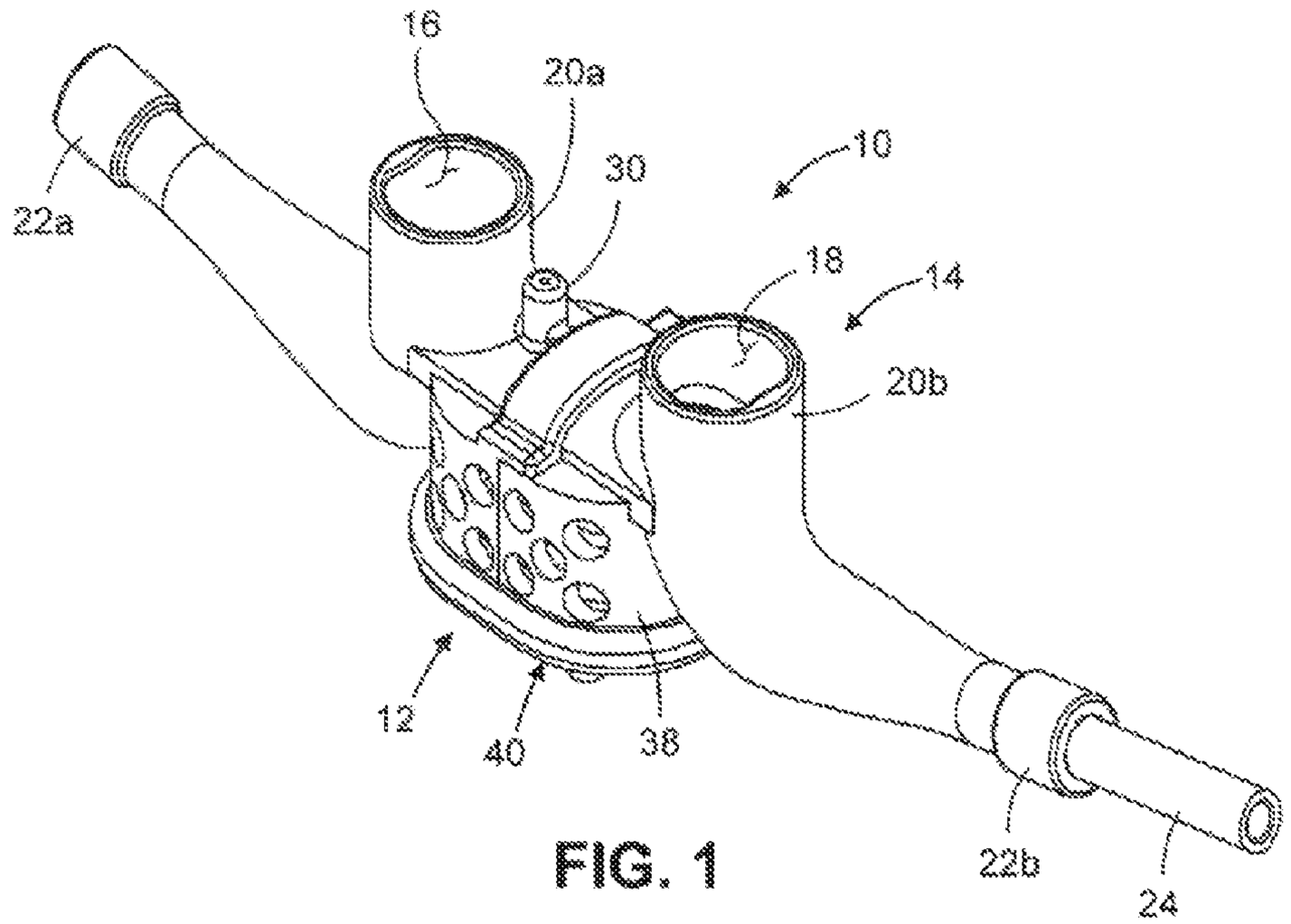
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14
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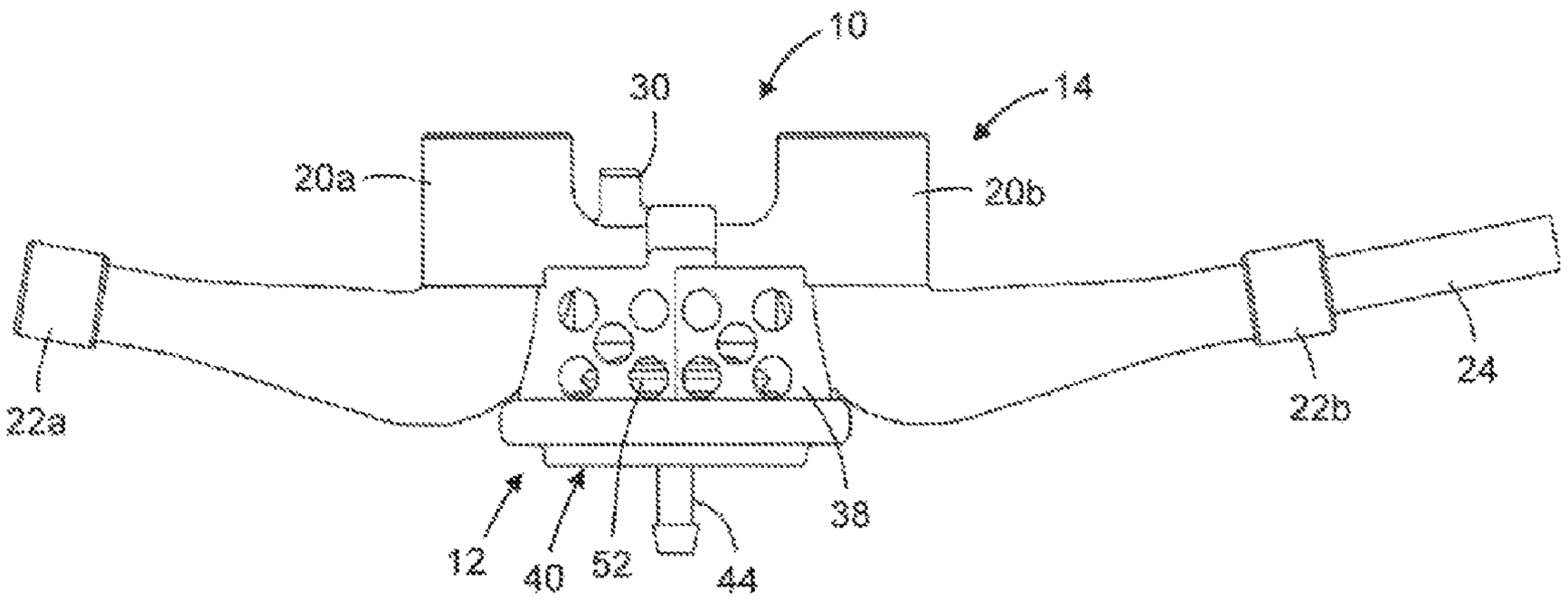
22b
24

FIG. 1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12
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44
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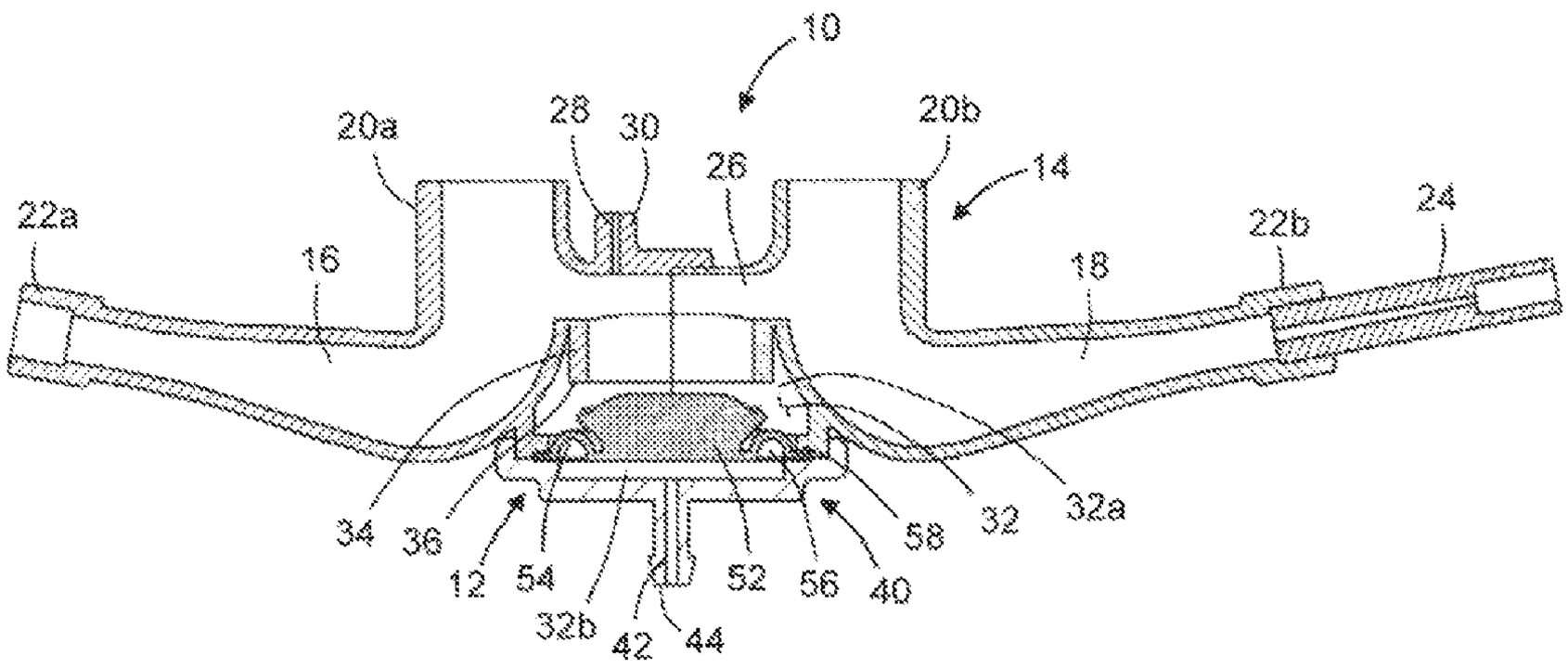
FIG. 2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20b
26
14
22a
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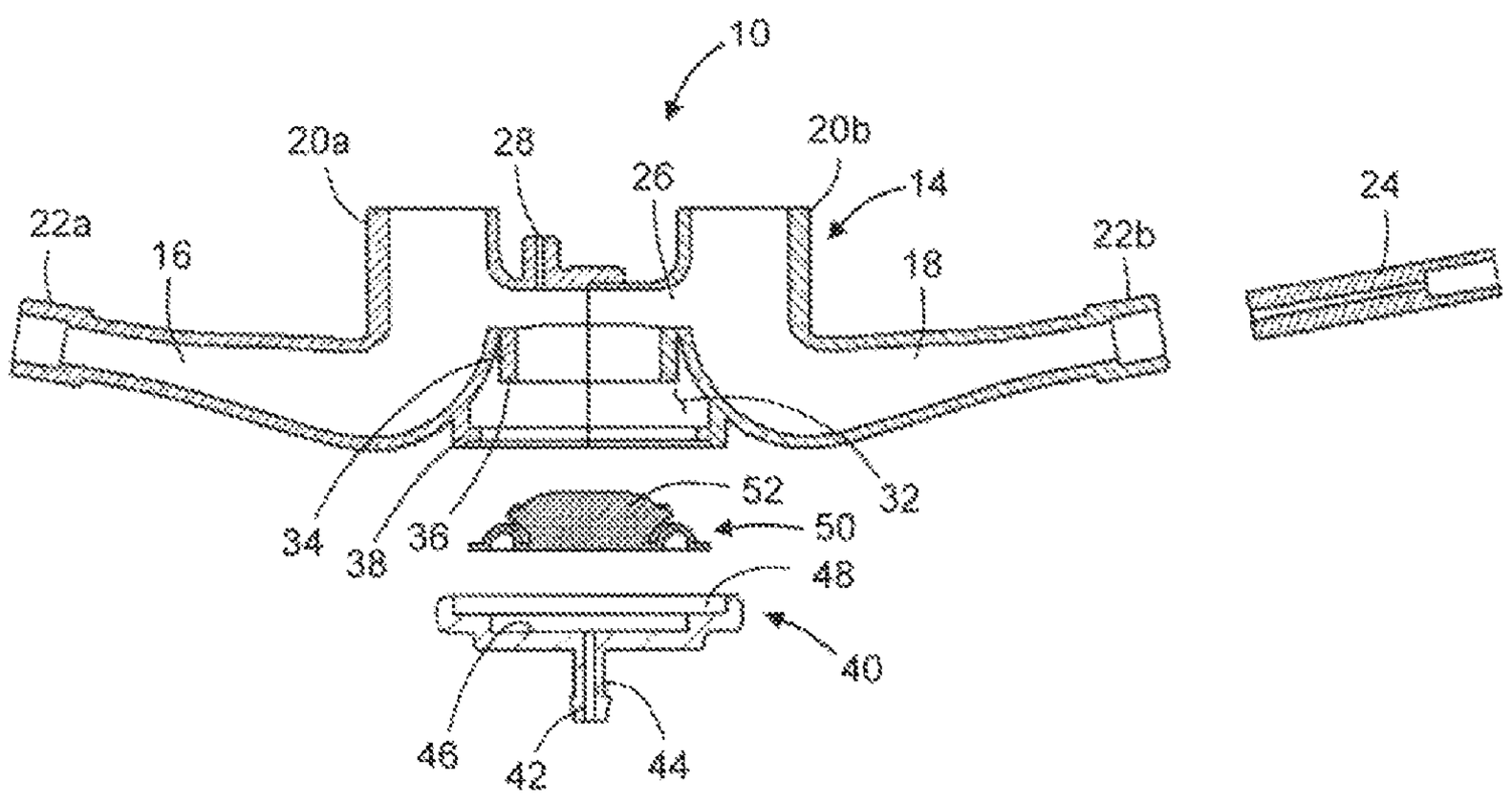
34
36
12
54
32b
42
44
52
56
40
58
32
32a

FIG. 3


10
20a
28
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20b
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46
42
44
32

FIG. 4

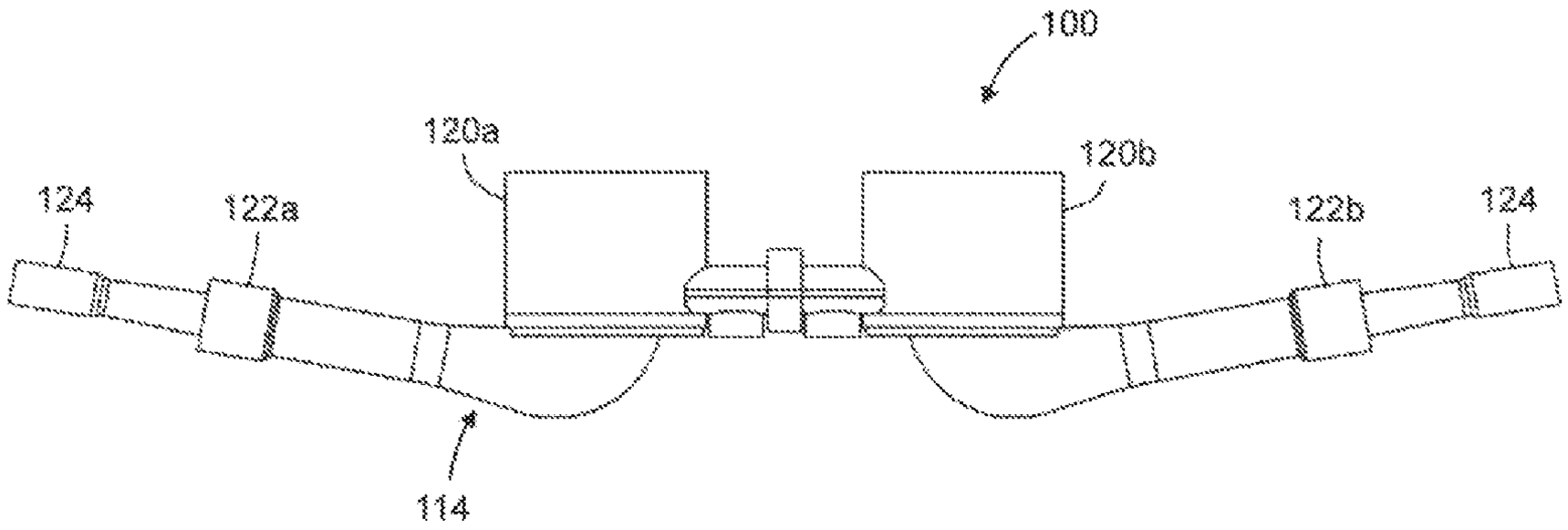


FIG. 5

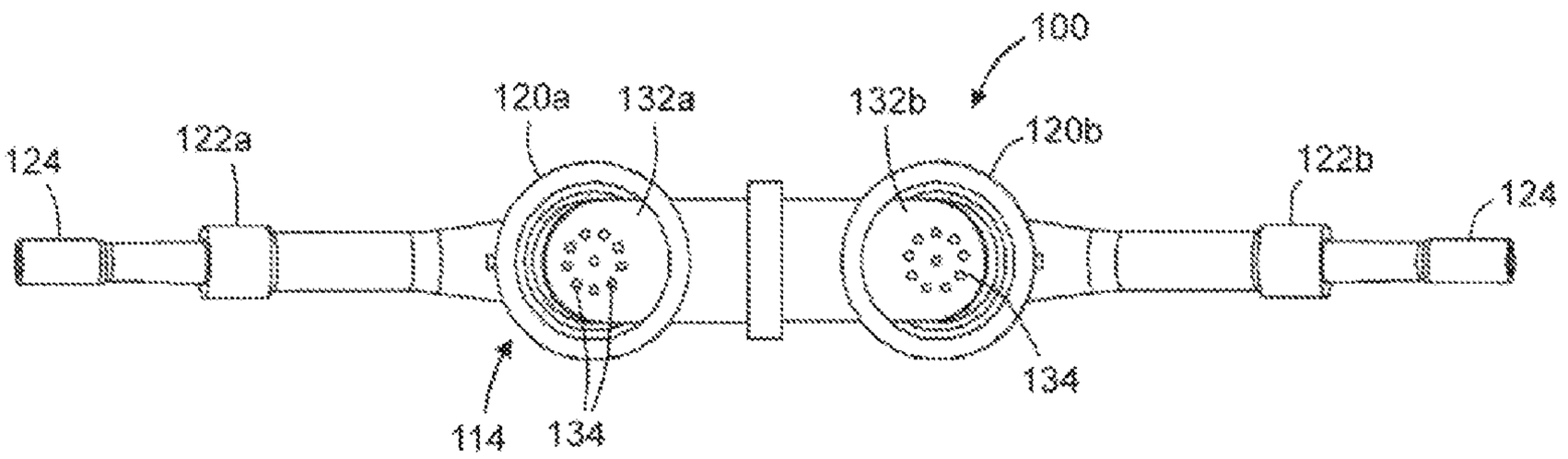


FIG. 6

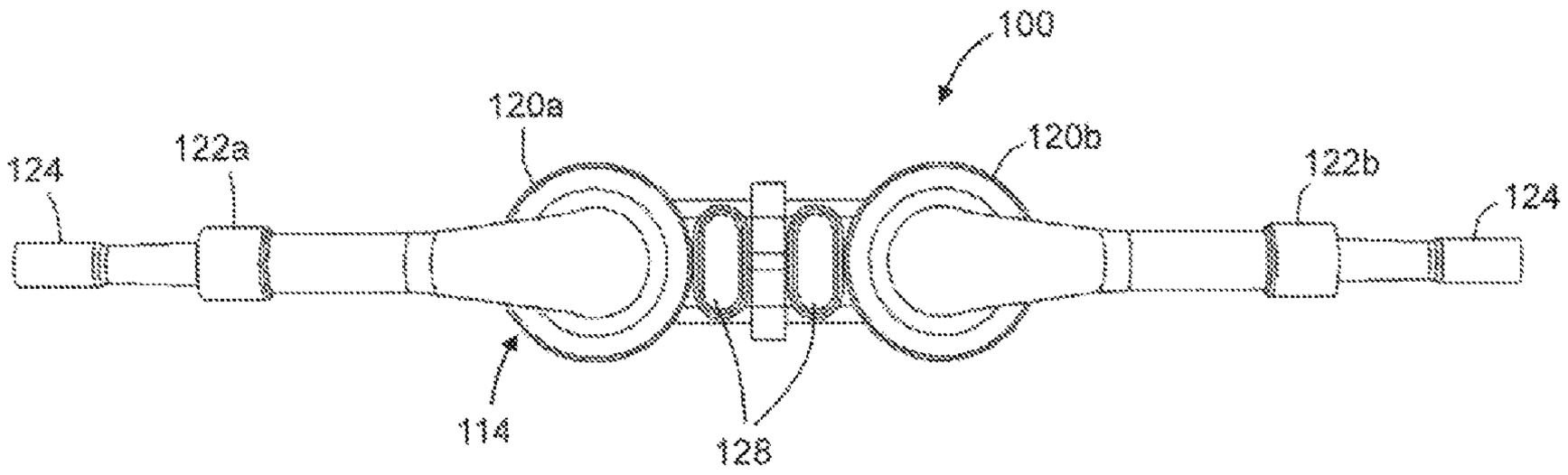
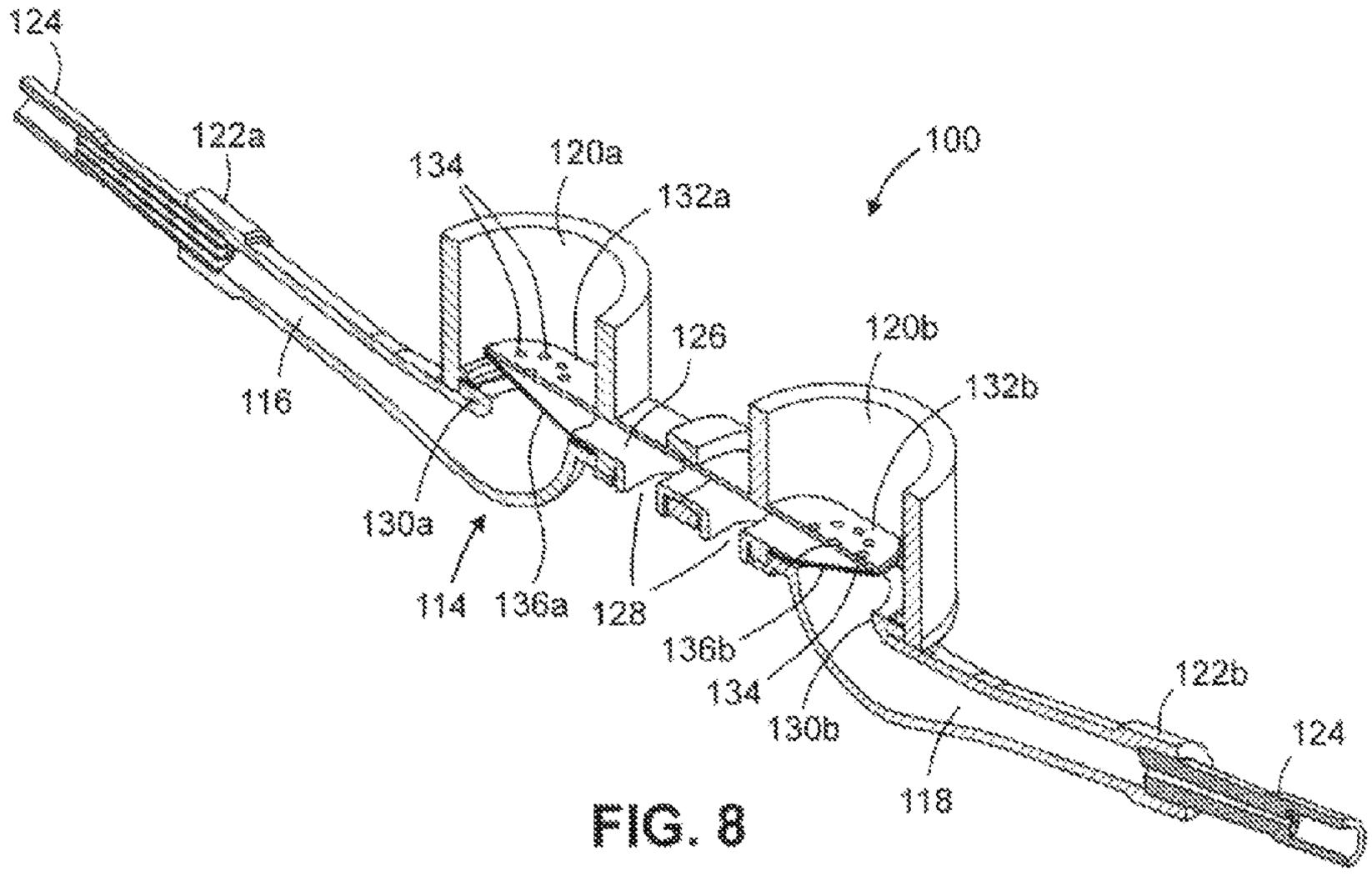


FIG. 7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122a
134
120a
132a
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120b
132b
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130a
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136a
128
136b
134
130b
122b
124
118

FIG. 8

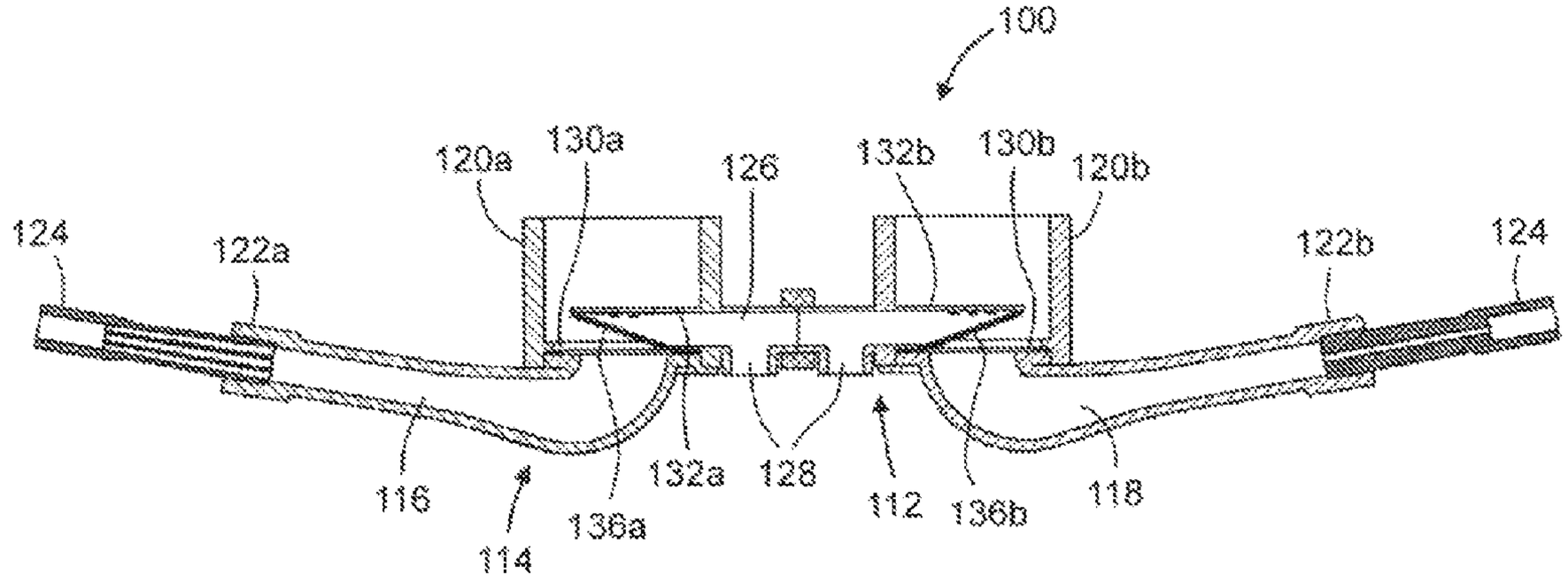
100
120a
130a
126
132b
130b
120b
124
122a
122b
124
116
132a
128
112
136b
118
114
136a

FIG. 9

VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE AND METHOD OF VENTILATING A PATIENT USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S. Provisional Patent Application Ser. No. 61/499,950 entitled VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE filed Jun. 22, 2011, and U.S. Provisional Patent Application Ser. No. 61/512,750 entitled VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE AND METHOD OF VENTILATING A PATIENT USING THE SAME filed Jul. 28, 2011

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to systems and methods for controlling delivery of a pressurized flow of breathable gas to a patient and, more particularly, to a ventilation mask such as a nasal mask, nasal prongs mask or nasal pillows mask for use in critical care ventilation, respiratory insufficiency or PAP (Positive Airway Pressure) therapy and incorporating a piloted exhalation valve inside the mask.

2. Description of the Related Art

As is known in the medical arts, mechanical ventilators comprise medical devices that either perform or supplement breathing for patients. Early ventilators, such as the "iron lung", created negative pressure around the patient's chest to cause a flow of ambient air through the patient's nose and/or mouth into their lungs. However, the vast majority of contemporary ventilators instead use positive pressure to deliver gas to the patient's lungs via a patient circuit between the ventilator and the patient. The patient circuit typically consists of one or two large bore tubes (e.g., 22 mm ID for adults; 15 mm ID for pediatric) that interface to the ventilator on one end and a patient mask on the other end. Most often, the patient mask is not provided as part of the ventilator system, and a wide variety of patient masks can be used with any ventilator. The interfaces between the ventilator, patient circuit and patient masks are standardized as generic 15 mm/22 mm conical connectors, the size and shape of which are specified by regulatory bodies to assure interoperability.

Current ventilators are designed to support either single limb or dual limb patient circuits. Ventilators using single limb patient circuit are most typically used for less acute clinical requirements, such as treatment of obstructive sleep apnea or respiratory insufficiency. Ventilators using dual limb patient circuits are most typically used for critical care applications.

Single limb patient circuits are used only to carry gas flow from the ventilator to the patient and patient mask, and require a patient mask with vent holes. The pressure/flow characteristics of the vent holes in the mask are maintained according to standards that assure interoperability of masks with a multitude of ventilators that follow the standard. When utilizing single limb circuits, the patient inspires fresh gas from the patient circuit, and expires CO2-enriched gas, which is purged from the system through the vent holes in the mask and partially breathed down the tube to the ventilator and re-breathed during the next breath. This constant purging of flow through vent holes in the mask when using single-limb circuits provides several disadvantages: 1) it requires the ventilator to provide significantly more flow than the patient requires, adding cost/complexity to the ventilator and requiring larger tubing; 2) the constant flow through the vent holes creates noise, which has proven to be a significant detriment to patients with sleep apnea that are trying to sleep with the mask, and also to their sleep partners; 3) the additional flow coming into proximity of the patient's nose and then exiting the system often causes dryness in the patient, which often drives the need for adding humidification to the system; and 4) patient-expired CO2 flows partially out of the vent holes in the mask and partially into the patient circuit tubing, requiring a minimum flow through the tubing at all times in order to flush the CO2. To address the problem of undesirable flow of patient-expired CO2 back into the patient circuit tubing, currently known CPAP systems typically have a minimum-required pressure of 4 cmH2O whenever the patient is wearing the mask, which produces significant discomfort, claustrophobia and/or feeling of suffocation to early CPAP users and leads to a high (approximately 50%) non-compliance rate with CPAP therapy.

When utilizing dual limb circuits, the patient inspires fresh gas from one limb (the "inspiratory limb") of the patient circuit and expires CO2-enriched gas from the second limb (the "expiratory limb") of the patient circuit. Both limbs of the dual limb patient circuit are connected together in a "Y" proximal to the patient to allow a single 15 mm or 22 mm conical connection to the patient mask.

In the patient circuits described above, the ventilator pressurizes the gas to be delivered to the patient inside the ventilator to the intended patient pressure, and then delivers that pressure to the patient through the patient circuit. Very small pressure drops develop through the patient circuit, typically around 1 cmH2O, due to gas flow though the small amount of resistance created by the 22 mm or 15 mm ID tubing. Some ventilators compensate for this small pressure either by mathematical algorithms, or by sensing the tubing pressure more proximal to the patient.

Ventilators that utilize a dual limb patient circuit typically include an exhalation valve at the end of the expiratory limb proximal to the ventilator. The ventilator controls the exhalation valve, closes it during inspiration, and opens it during exhalation. Less sophisticated ventilators have binary control of the exhalation valve, in that they can control it to be either open or closed. More sophisticated ventilators are able to control the exhalation valve in an analog fashion, allowing them to control the pressure within the patient circuit by incrementally opening or closing the valve. Valves that support this incremental control are referred to as active exhalation valves. In existing ventilation systems, active exhalation valves are most typically implemented physically within the ventilator, and the remaining few ventilation systems with active exhalation valves locate the active exhalation valve within the patient circuit proximal to the ventilator. Active exhalation valves inside ventilators are typically actuated via an electromagnetic coil in the valve, whereas active exhalation valves in the patient circuit are typically pneumatically piloted from the ventilator.

BRIEF SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a mask for achieving positive pressure mechanical

ventilation (inclusive of PAP, ventilatory support, critical care ventilation, emergency applications), and a method for a operating a ventilation system including such mask. The mask may include a pressure sensing modality proximal to the patient connection. Such pressure sensing modality may be a pneumatic port with tubing that allows transmission of the patient pressure back to the ventilator for measurement, or may include a transducer within the mask. The pressure sensing port, if included in the mask, is used in the system to allow pressure sensing for achieving and/or monitoring the therapeutic pressures. Alternately or additionally, the mask may include a flow sensing modality located therewithin for achieving and/or monitoring the patient and/or therapeutic flows.

The mask of the present invention also includes a piloted exhalation valve that is used to achieve the target pressures/flows to the patient. In the preferred embodiment, the pilot for the valve is pneumatic and driven from the gas supply tubing from the ventilator. The pilot can also be a preset pressure derived in the mask, a separate pneumatic line from the ventilator, or an electro-mechanical control. In accordance with the present invention, the valve can be implemented with a diaphragm or with a flapper.

One of the primary benefits attendant to including the valve inside the mask is that it provides a path for patient-expired CO2 to exit the system without the need for a dual-limb patient circuit, and without the disadvantages associated with traditional single-limb patient circuits. For instance, in applications treating patients with sleep apnea, having the valve inside the mask allows patients to fall asleep while wearing the mask without the treatment pressure turned on, thereby preventing patient discomfort typically experienced with falling asleep while breathing at a positive pressure. In accordance with the present invention, the sensing described above may be used to sense a predetermined event, such as a set time, the detection of an event indicating patient airway obstruction, or the detection of a patient falling asleep, and start the positive airway pressure therapy upon sensing any such event, unlike existing devices which attempt to alleviate patient discomfort by starting at a lower pressure level (typically 4 cmH2O) and ramping the pressure up to a therapeutic level over a period of time. Additionally, having a valve inside the mask mitigates the need to have vent holes within the patient mask (a typical feature of mask used for sleep apnea) coincident with a purge flow to bleed patient expired CO2 from the system. Alleviating the mask vent holes and associated extra flow of gas through the mask helps reduce noise generated by the mask, reduce CO2 re-breathing, reduce patient nose dryness cause by excess gas flowing past the patient, and reduce flow requirements of the ventilator. Yet another benefit of the mask without vent holes and having the valve inside the same is that because there is not a constant flow through the mask and out of any vent holes, a heat moisture exchanger can also be incorporated into the mask, allowing a simple method of providing heated and humidified gas to the patient.

Another benefit for having the valve inside the mask is that it allows for a significant reduction in the tubing size, as it supports the ventilator delivering higher pressures than the patient's therapeutic pressure. In this regard, pressure from the ventilator is significantly higher than the patient's therapeutic pressure. Pressure sensing can be implemented inside the mask near the patient interface port(s), facilitating the ventilator to have a means to servo control pressure at the patient interface port(s). Having higher pressure from the ventilator and an active exhalation valve in the mask allows for the tubing size to be significantly smaller (e.g. 1-9 mm ID) compared to conventional ventilators (22 mm ID for adults/15 mm ID for pediatric). One obvious benefit of smaller tubing is that it provides less bulk for patient and/or caregivers to manage. For today's smallest ventilators, the bulk of the tubing is as significant as the bulk of the ventilator. Another benefit of the smaller tubing is that is allows for more convenient ways of affixing the mask to the patient. For instance, the tubing can go around the patient's ears to hold the mask to the face, instead of requiring straps (typically called "headgear") to affix the mask to the face. Along these lines, the discomfort, complication, and non-discrete look of the headgear is another significant factor leading to the high non-compliance rate for CPAP therapy. Another benefit to the smaller tubing is that the mask can become smaller because it does not need to interface with the large tubing. Indeed, large masks are another significant factor leading to the high non-compliance rate for CPAP therapy since, in addition to being non-discrete, they often cause claustrophobia.

The present invention is best understood by reference to the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

FIG. **1** is an isometric view of a nasal pillows mask constructed in accordance with a first embodiment of the present invention and including an integrated diaphragm-implementation piloted exhalation valve;

FIG. **2** is a front elevational view of the nasal pillows mask shown in FIG. **1**;

FIG. **3** is a cross-sectional view of the nasal pillows mask shown in FIG. **2**;

FIG. **4** is an exploded, cross-sectional front view of the nasal pillows mask shown in FIG. **3**;

FIG. **5** is a front elevational view of a nasal pillows mask constructed in accordance with a second embodiment of the present invention and including an integrated flapper-implementation exhalation valve;

FIG. **6** is a top plan view of the nasal pillows mask shown in FIG. **5**;

FIG. **7** is a bottom plan view of the nasal pillows mask shown in FIG. **5**;

FIG. **8** is a cross-sectional, isometric view of the nasal pillows mask shown in FIG. **5**; and

FIG. **9** is a cross-sectional view of the nasal pillows mask shown in FIG. **5**.

Common reference numerals are used throughout the drawings and detailed description to indicate like elements.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings wherein the showings are for purposes of illustrating various embodiments of the present invention only, and not for purposes of limiting the same, FIGS. **1-4** depict a ventilation mask **10** constructed in accordance with a first embodiment of the present invention. The mask is depicted as a nasal prongs mask, however those skilled in the art will recognize that other ventilation masks are contemplated herein such as nasal pillows masks, nasal masks and oronasal masks and for purposes of this application the term mask and/or ventilation mask will include all

such mask structures. Additionally, for purposes of this application, the term "direct nasal interface mask" will be deemed to encompass those masks which are configured to facilitate the direct introduction of therapeutic fluid pressure into the nostrils of a patent, such masks including, but not being limited to, nasal pillows masks, nasal prongs masks, and nasal cradle masks. The mask **10** includes an integrated, diaphragm-implemented, piloted exhalation valve **12**, the structural and functional attributes of which will be described in more detail below.

As seen in FIGS. **1-4**, the mask **10** comprises a housing **14** which defines first and second fluid flow passages **16**, **18**. As best seen in FIGS. **3** and **4**, the flow passages **16**, **18** are formed within the housing **14** to have substantially identical shapes or contours. Although illustrated with a pair of flow passages, **16**, **18**, those skilled in the art will recognize that a single flow passage is additionally contemplated herein. In the mask **10**, one end of each of the flow passages **16**, **18** is defined by a respective one of an identically configured pair of generally cylindrical, tubular protrusions **20***a*, **20***b* of the housing **14**. The opposite end of each of the flow passages **16**, **18** is defined by a respective one of an identically configured pair of connector ports **22***a*, **22***b* of the housing **14**. As seen in FIGS. **3** and **4**, the connector ports **22***a*, **22***b* are each sized and configured to accommodate the advancement of a distal end portion of a tubular fluid line **24** therein. As is apparent from FIG. **3**, the operative engagement of a fluid line **24** to each of the connector ports **22***a*, **22***b* effectively places such fluid lines **24** into fluid communication with respective ones of the flow passages **16**, **18**. In the housing **14**, the spacing between the protrusions **20***a*, **20***b* is selected to facilitate the general alignment thereof with the nostrils of an adult patient when the mask **10** is worn by such patient.

In the mask **10**, the flow passages **16**, **18** are preferably not fluidly isolated from each other. Rather, as also seen in FIGS. **3** and **4**, the housing **14** may define an optional cross passage **26** which extends between the protrusions **20***a*, **20***b* thereof, and effectively places the flow passages **16**, **18** into fluid communication with each other. The cross passage **26** is further placed into fluid communication with ambient air by an optional vent port **28** which is fluidly coupled thereto. The vent port **28** is defined by and extends axially through a generally cylindrical boss **30** of the housing **14** which protrudes upwardly between the protrusions **20***a*, **20***b* thereof.

The housing **14** of the mask **10** further defines an internal valve chamber **32** which fluidly communicates with the cross passage **26**. As further seen in FIGS. **3** and **4**, disposed at the junction between the cross passage **26** and valve chamber **32** is a tubular projection **34** of the housing **14**. The projection **34** defines an annular distal rim or seating surface **36** which is used in the operation of the valve **12** in manner which will be described in more detail below. The projection **34** protrudes into the valve chamber **32**, and defines the conduit which places the valve chamber **32** into fluid communication with the cross passage **26**.

As best seen in FIGS. **3** and **4**, the valve chamber **32** is defined in large measure by a valve wall **38** of the housing **14** which is generally oriented between the flow passages **16**, **18** thereof and, when viewed from the perspective shown in FIGS. **1-4**, is disposed below the cross passage **26**. As is also apparent from FIGS. **1** and **2**, the valve wall **38** has a perforated construction, thus facilitating the fluid communication between the valve chamber **32** partially defined thereby and ambient air.

In the mask **10**, the end of the valve chamber **32** disposed furthest from the cross passage **26** is enclosed by a valve cap **40** which may be removably attached or permanently attached to the distal portion or rim of the valve wall **38** in the manner best seen in FIG. **3**. The valve cap **40** includes a pilot port **42** which, when the valve cap **40** is coupled to the valve wall **38**, is placed into fluid communication with the valve chamber **32**. The pilot port **42** is partially defined by and extends axially through a generally cylindrical connector **44** of the valve cap **40**. As best seen in FIGS. **3** and **4**, one end of the pilot port **42** is disposed within a generally planar base surface **46** defined by the valve cap **40**. In addition to the base surface **46**, the valve cap **40** defines a continuous shoulder **48** which, from the perspective shown in FIG. **4**, is elevated above the base surface **46**. This embodiment shows a pneumatically piloted diaphragm; it is additionally contemplated that the valve **12** can be driven in an electromechanical manner (e.g., with an electromagnet instead of using the above mentioned pilot port **42**).

The mask **10** of the present invention further comprises a diaphragm **50** which resides within the valve chamber **32**. Although various configurations of diaphragms **50** are contemplated herein, as is also best seen in FIGS. **3** and **4**, the diaphragm **50** has an enlarged, central main body portion **52**, and a peripheral flange portion **54** which is integrally connected to and circumvents the main body portion **52**. The flange portion **54** includes an arcuately contoured central region which is oriented between the distal region thereof and the main body portion **52**, and defines a continuous, generally concave channel **56**. The diaphragm **50** is preferably fabricated from a suitable resilient material.

In the mask **10**, the distal region of the flange portion **54** of the diaphragm **50** which is disposed outward of the arcuate central region thereof is normally captured between the valve cap **40** and the valve wall **38** when the valve cap **40** is operatively engaged to the valve wall **38**. More particularly, as seen in FIG. **3**, the distal region of the flange portion **54** is compressed and thus captured between the shoulder **48** of the valve cap **40** and a lip portion **58** of the valve wall **38** which protrudes inwardly from the inner surface thereof. The diaphragm **50** is preferably sized such that when the distal region of the flange portion **54** thereof is captured between the shoulder **48** and lip portion **58** in the aforementioned manner, the arcuate central region of the flange portion **54** is disposed directly adjacent the inner peripheral surface of the lip portion **58**. Additionally, the channel **56** defined by the flange portion **54** is directed toward and thus faces the base surface **46** of the valve cap **40**.

In the mask **10**, the diaphragm **50** effectively segregates the valve chamber **32** into a patient side or region **32***a*, and a pilot side or region **32***b*. More particularly, due to the aforementioned manner in which the diaphragm **50** is captured between the valve cap **40** and the valve wall **38**, the patient and pilot regions **32***a*, **32***b* of the valve chamber **32** are separated from each other by the diaphragm **50**, and are of differing volumes. Along these lines, the fluid conduit defined by the projection **34** communicates directly with the patient region **32***a* of the valve chamber **32**, while the pilot port **42** defined by the connector **44** communicates directly with the pilot region **32***b* of the valve chamber **32**.

The diaphragm **50** (and hence the valve **12**) is selectively moveable between an open position (shown in FIG. **3**) and a closed position. Importantly, in either of its open or closed positions, the diaphragm **50** is not seated directly against the base surface **46** of the valve cap **40**. Rather, a gap is normally maintained therebetween. As seen in FIG. **3**, the width of

such gap when the diaphragm **50** is in its open position is generally equal to the fixed distance separating the base surface **46** of the valve cap **40** from the shoulder **48** thereof. When the diaphragm **50** is in its open position, it is also disposed in spaced relation to the projection **34** of the housing **14**, and in particular the seating surface **36** defined thereby. As such, when the diaphragm **50** is in its open position, fluid is able to freely pass between the flow passages **16**, **18** and ambient air via the cross passage **26**, the flow conduit defined by the projection **34**, and the perforated openings within the valve wall **38** partially defining the valve chamber **32**.

The diaphragm **50** may be resiliently deformable from its open position (to which it may be normally biased) to its closed position. It is an important feature of the present invention that the diaphragm **50** is normally biased in its open position which provides a fail safe to allow a patient to inhale ambient air through the valve and exhale ambient air through the valve even during any ventilator malfunction.

When moved or actuated to the closed position, the main body portion **52** of the diaphragm **50** is firmly seated against the seating surface **36** defined by the projection **34**, thus effectively blocking fluid communication between the cross passage **26** (and hence the flow passages **16**, **18**) and the valve chamber **32**. More particularly, when viewed from the perspective shown in FIG. **3**, the peripheral region of the top surface of the main body portion **52** is seated against the seating surface **36**, with a central region of the top surface of the main body portion **52** protruding slightly into the interior of the projection **34**, i.e., the fluid conduit defined by the projection **34**.

As is apparent from the foregoing description, in the mask **10**, the valve **12** thereof is collectively defined by the projection **34**, valve wall **38**, valve cap **40** and diaphragm **50**. Additionally, in the mask **10**, it is contemplated that the valve **12** will be piloted, with the movement of the diaphragm **50** to the closed position as described above being facilitated by the introduction of positive fluid pressure into the gap normally defined between the diaphragm **50** and the base surface **46** via the pilot port **42**, i.e., into the pilot region **32***b* of the valve chamber **32**. In this regard, it is contemplated that during the use of the mask **10** by a patient, a pilot fluid line (not shown) from a ventilator will be coupled to the connector **44**. It is also contemplated that during the inspiratory phase of the breathing cycle of the patient wearing the mask **10**, the fluid pressure level introduced into the pilot region **32***b* of the valve chamber **32** via the pilot port **42** will be sufficient to facilitate the movement of the diaphragm **50** to its closed position. Conversely, during the expiratory phase of the breathing cycle of the patient wearing the mask **10**, it is contemplated that the discontinuation of the fluid flow through the pilot port **42**, coupled with the resiliency of the diaphragm **50**, a biasing spring (not shown) operatively coupled to the main body portion **52** of the diaphragm **50**, and/or positive pressure applied to the main body portion **52** of the diaphragm **50**, will facilitate the movement of the diaphragm **50** back to the open position. As will be recognized, the movement of the diaphragm **50** to the open position allows the air exhaled from the patient to be vented to ambient air after entering the patient region **32***a* of the valve chamber **32** via the perforated openings of the valve wall **38** communicating with the valve chamber **32**.

As will be recognized, based upon the application of pilot pressure, the diaphragm **50** travels from a fully open position through a partially open position to a fully closed position. In this regard, the diaphragm **50** will be partially open or partially closed during exhalation to maintain desired ventilation therapy. Additionally, a positive airway pressure can be controlled with any expiratory flow value by modulating the pilot pressure within the pilot region **32***b* of the valve chamber **32** and hence the position of the diaphragm **50**. Further, when pilot pressure is discontinued to the diaphragm, the diaphragm **50** moves to an open position wherein the patient can inhale and exhale through the mask with minimal restriction and with minimal carbon dioxide retention within the mask **10**. This is an important feature of the present invention which allows a patient to wear the mask **10** without ventilation therapy being applied to the mask such that the mask **10** is comfortable to wear and can be worn without carbon dioxide buildup. This feature is highly advantageous for the treatment of obstructive sleep apnea where patients complain of discomfort with ventilation therapy due to mask and pressure discomfort. When it is detected that a patient requires sleep apnea therapy, the ventilation therapy can be started (i.e., in an obstructive sleep apnea situation).

In this regard, the present invention contemplates a method of ventilation utilizing a mask wherein patient inhalation and patient exhalation is facilitated through the mask to ambient air when the ventilator is not delivering a therapeutic level of pressure. For instance, additional valving in the mask may be implemented for this purpose. Since the mask does not facilitate CO2 buildup, the ventilator can remain off while the mask is worn by the patient and ventilation therapy can be initiated upon sensing or detecting a patient requirement, such as sleep apnea therapy, by conventional sensors incorporated into the mask and ventilator. In this regard, conventional ventilators can be readily modified via conventional software changes to allow the mask to be worn without supplying pressure to the mask unless and until a patient requirement is sensed and subsequently communicated to the ventilator to provide necessary ventilation to the patient. Such modification may additionally require the use of a conventional check valve to ensure that patient exhalation is facilitated through the exhalation valve on the mask and not back into the ventilator delivery circuit.

As indicated above, in the embodiment shown in FIGS. **1-4**, the diaphragm **50** is pneumatically piloted, with the position thereof being regulated by selectively modulating the pilot pressure within the pilot region **32***b* of the valve chamber **32**. However, it is contemplated that alternative modalities, such as an electromagnetic actuator, can be used to drive the valve **12**. For example, as also indicated above, in an alternative embodiment, the valve **12** may be driven in an electromechanical manner through the use of an electromagnet instead of using the above-described pilot port **42**.

As indicated above, in the mask **10**, the valve cap **40** is releasably attached to the valve wall **38** of the housing **14**. As a result, the selective detachment of the valve cap **40** from the housing **14** allows for the removal of the diaphragm **50** from within the valve chamber **32** as permits the periodic cleaning or disinfection thereof. In addition, the detachment of the valve cap **40** from the valve wall **38** of the housing **14** also permits access to and the cleaning or disinfection of the interior surfaces of the valve chamber **32**. Port **28** provides a means for pressure measurement inside the mask, and thus may optionally serve as a pressure sensing port.

Referring now to FIGS. **5-9**, there is shown a nasal pillows mask **100** constructed in accordance with a second embodiment of the present invention. The mask **100** includes an integrated, flapper-implemented exhalation valve **112**, the structural and functional attributes of which will be described in more detail below.

As seen in FIGS. **5-9**, the mask **100** comprises a housing **114** which defines first and second fluid flow passages **116**, **118**. As seen in FIGS. **8** and **9**, the flow passages **116**, **118** are formed within the housing **114** to have substantially identical shapes or contours. As with the first embodiment of this invention, a single flow passage is additionally expressly contemplated herein. In the mask **100**, one end of each of the flow passages **116**, **118** is defined by a respective one of an identically configured pair of generally cylindrical, tubular protrusions **120***a*, **120***b* of the housing **114**. The opposite end of each of the flow passages **116**, **118** is defined by a respective one of an identically configured pair of connector ports **122***a*, **122***b* of the housing **114**. The connector ports **122***a*, **122***b* are each sized and configured to accommodate the advancement and frictional retention of a distal end portion of a tubular fluid line **124** therein. As most apparent from FIGS. **8** and **9**, the operative engagement of a fluid line **124** to each of the connector portions **122***a*, **122***b* effectively places such fluid lines **124** into fluid communication with respective ones of the flow passages **116**, **118**. In the housing **114**, the spacing between the protrusions **120***a*, **120***b* is selected to facilitate the general alignment thereof with the nostrils of an adult patient when the mask **100** is worn by such patient.

In the mask **100**, the flow passages **116**, **118** are not fluidly isolated from each other. Rather, as seen in FIGS. **8** and **9**, the housing **114** further defines an optional cross passage **126** which extends between the protrusions **120***a*, **120***b* thereof, and effectively places the flow passages **116**, **118** into fluid communication with each other. The cross passage **126** is further placed into communication with ambient air by an identically configured pair of vent ports **128** which are fluidly coupled thereto. The vent ports **128**, which are disposed in side-by-side, spaced relation to each other, are formed within the housing **14** between the protrusions **120***a*, **120***b* thereof and, when viewed from the perspective shown in FIG. **9**, face downwardly in a direction opposite that of the open distal ends of the protrusions **120***a*, **120***b*.

As is best seen in FIGS. **8** and **9**, the protrusions **120***a*, **120***b* are preferably formed as separate and distinct components or sections of the housing **114** which, when mated to the remainder thereof, facilitate the formation of an identically configured pair of arcuate, semi-circular shoulders **130***a*, **130***b*. The shoulders **130***a*, **130***b* defined by the housing **114** are located within the interiors of respective ones of the protrusions **120***a*, **120***b* thereof. More particularly, each shoulder **130***a*, **130***b* is formed in close proximity to that end of the corresponding protrusion **120***a*, **120***b* disposed furthest from the open distal end thereof. The use of the shoulders **130***a*, **130***b* will be described in more detail below.

In the mask **100**, the cross passage **126** is partially defined by one or more valve projections **132***a*, **132***b* of the housing **114** which are integrally connected to respective ones of the protrusions **120***a*, **120***b*, and protrude generally perpendicularly from the inner surfaces thereof in opposed relation to each other. As seen in FIGS. **6**, **8**, and **9**, the valve projections **132***a*, **132***b* are not sized to completely span or cover those portions of the flow passages **116**, **118** defined by the protrusions **120***a*, **120***b*. Rather, each of the valve projections **132***a*, **132***b* is formed to define an arcuate peripheral edge segment, and sized such that the arcuate peripheral edge segment thereof is separated or spaced from the inner surface of the corresponding protrusion **120***a*, **120***b* by a gap which is of a prescribed width. Further, as seen in FIGS. **6** and **8**, each of the valve projections **132***a*, **132***b* preferably includes a plurality of flow openings **134** disposed therein in a generally circular pattern. The flow openings **134** of the valve projections **132***a*, **132***b* each fluidly communicate with the cross passage **126**, and are used for purposed which will also be described in more detail below.

The mask **100** of the present invention further comprises a flapper, which is preferably segregated into an identically configured pair of flapper segments **136***a*, **136***b*. The flapper segments **136***a*, **136***b* are each preferably fabricated from a suitable, resilient material. As seen in FIGS. **8** and **9**, the flapper segments **136***a*, **136***b* reside within the interiors of respective ones of the protrusions **120***a*, **120***b*. Additionally, when viewed from the perspective shown in FIGS. **8** and **9**, an inner end portion of each of the flapper segments **136***a*, **136***b* is firmly secured to the housing **114** as a result of being captured between prescribed components or sections thereof. However, those portions of the flapper segments **136***a*, **136***b* not rigidly secured to the housing **114** are free to resiliently move relative thereto, in a manner which will be described in more detail below.

The flapper segments **136***a*, **136***b* (and hence the valve **112**) are selectively moveable between a closed position (shown in FIGS. **8** and **9**) and an open position. When the flapper segments **136***a*, **136***b* are each in the open position, that portion of the peripheral edge thereof not secured to the housing **114** (i.e., not captured between separate sections of the housing **114**) is normally seated against a corresponding one of the shoulders **130***a*, **130***b*. As a result, any fluid (e.g., air exhaled from the nose of a patient wearing the mask) flowing into the flow passages **116**, **118** via the open distal ends of the protrusions **120***a*, **120***b* is vented to ambient air via the cross passage **126** and vent ports **128**. In this regard, such fluid is able to enter the cross passage **126** through the gaps defined between the valve projections **132***a*, **132***b* and inner surfaces of the corresponding protrusions **120***a*, **120***b*.

The flapper segments **136***a*, **136***b* may be resiliently deformable from the open position described above (to which they are normally biased) to the closed position shown in FIGS. **8** and **9**. More particularly, when moved or actuated to the closed position, those portions of the flapper segments **136***a*, **136***b* not secured to the housing **114** are effectively placed into sealed contact with peripheral portions of respective ones of the valve projections **132***a*, **132***b* in a manner substantially covering or obstructing the opposed ends of the cross passage **126** fluidly communicating the flow passages **116**, **118**. However, even when the flapper segments **136***a*, **136***b* are in the closed position, some measure of fluid may still be vented from the flow passages **116**, **118** to ambient air by entering the cross passage **126** via the flow openings **134** included in each of the valve projections **132***a*, **132***b*.

As is apparent from the foregoing description, in the mask **100**, the valve **112** thereof is collectively defined by the shoulders **130***a*, **130***b*, valve projections **132***a*, **132***b*, and flapper segments **136***a*, **136***b* of the flapper. Additionally, in the mask **100**, it is contemplated that the flapper segments **136***a*, **136***b* will normally be biased to the open position. In this regard, it is contemplated that during the inspiratory phase of the breathing cycle of a patient using the mask **100**, positive fluid pressure introduced into the flow passages **116**, **118** by a ventilator fluidly coupled thereto via the fluid lines **124** will act against the flapper segments **136***a*, **136***b* in a manner facilitating the movement of such flapper segments **136***a*, **136***b* from their normally open position, to the closed position shown in FIGS. **8** and **9**. As a result, fluid is able to flow freely through the flow passages **116**, **118** into the patient's nostrils, and is substantially prevented from being vented to ambient air via the cross passage **126**, except for

a small portion of flow that passes through flow openings **134**. This small flow through flow openings **134** provides for a means to bleed off pressure and therefore more easily control the valve.

Conversely, during the expiratory phase of the breathing cycle of the patient wearing the mask **100**, it is contemplated that a reduction in the fluid pressure level introduced into the flow passages **116**, **118** from the fluid lines **124** to below a prescribed level will allow the flapper segments **136***a*, **136***b* to resiliently return to their normal, open positions engaging respective ones of the shoulders **130***a*, **130***b*. When the flapper segments **136***a*, **136***b* return to their open positions, air exhaled from the patient's nostrils during the expiratory phase of the patient's breathing circuit is vented to ambient air via the cross passage **126** and vent ports **128**. In this regard, though the movement of the flapper segments **136***a*, **136***b* to the open positions effectively blocks those portions of the flow passages **116**, **118**, air exhaled from the patient is able to flow through the gaps defined between the valve projections **132***a*, **132***b* and the inner surfaces of the protrusions **120***a*, **120***b*, and hence into the opposed open ends of the cross passage **126**.

Advantageously, the mask **100** constructed in accordance with the present invention has a total flow requirement which is much lower in comparison to that of a traditional vented PAP mask. This provides the mask **100** with several advantages, including: reduced flow from the ventilator, and thus the ability to use smaller tubes; a reduction in the conducted noise from the ventilator to ambient air through the open vent ports **128** in the mask **100**; a reduction in oxygen consumption when required with the PAP therapy due to lower flow requirements; and a reduction in water consumption of a humidifier due to lower flow requirements.

This disclosure provides exemplary embodiments of the present invention. The scope of the present invention is not limited by these exemplary embodiments. Numerous variations, whether explicitly provided for by the specification or implied by the specification, such as variations in structure, dimension, type of material and manufacturing process may be implemented by one of skill in the art in view of this disclosure.

What is claimed is:

1. A method of ventilating a patient utilizing a direct nasal interface mask worn by the patient and fluidly connected to a ventilator adapted to supply a pressurized, breathable gas to the direct nasal interface mask, the method comprising the steps of:

a) providing the direct nasal interface mask with a housing defining at least one flow passage, and a piloted exhalation valve is integrated into the housing and fluidly coupled to the flow passage; and

b) applying a pilot pressure to the exhalation valve via the ventilator and in a manner which facilitates the selective movement thereof from an open position to which it is normally biased and wherein at least a portion of the flow passage is vented to ambient air, to a closed position wherein fluid flow between the flow passage and ambient air is at least partially obstructed thereby.

2. The method of claim **1** wherein step (a) comprises configuring the exhalation valve to completely obstruct fluid flow between the flow passage and ambient air when moved to the closed position in step (b).

3. The method of claim **1** wherein step (a) comprises configuring the exhalation valve to vent the entirety of the flow passage to ambient air when moved to the open position in step (b).

4. The method of claim **1** wherein step (a) comprises configuring the exhalation valve to adjust fluid flow between the flow passage and ambient air when disposed between the closed position and open position in step (b).

5. The method of claim **1** wherein step (a) comprises configuring the housing to include a pressure sensing port, and step (b) comprises sensing pressure within the flow passage through the use of the pressure sensing port to facilitate at least one of achieving and monitoring a therapeutic pressure level therein.

6. The method of claim **1** wherein step (a) comprises configuring the exhalation valve to include a diaphragm which is movable between the closed and open positions in step (b).

7. The method of claim **1** wherein step (a) comprises configuring the exhalation valve to include at least one flapper which is movable between the closed and open positions in step (b).

8. The method of claim **1** wherein step (b) comprises initially supplying no pressurized, breathable gas from the ventilator to the patient via the direct nasal interface mask.

9. The method of claim **8** further comprising the step of:

c) initiating the delivery of the pressurized, breathable gas from the ventilator to the patient at a prescribed therapeutic pressure level upon an occurrence of a predetermined event.

10. The method of claim **9** wherein the predetermined event of step (c) is at least one of:

an elapse of a set time interval;

a detection of a patient breathing pattern indicative of an airway obstruction in the patient; and

a detection of a patient breathing pattern indicative of the patient falling asleep.

11. A method of ventilating a patient using a direct nasal interface mask worn by the patient and fluidly connected to a ventilator adapted to supply a pressurized, breathable gas to the direct nasal interface mask, the method comprising the steps of:

a) providing the direct nasal interface mask with a housing at least partially defining a valve chamber which fluidly communicates with ambient air, a pilot port which fluidly communicates with the valve chamber, at least one flow passage which is selectively placeable into fluid communication with the valve chamber, and a diaphragm which is disposed within the valve chamber and selectively movable from an open position to which it is normally biased and wherein the flow passage is vented to ambient air via the valve chamber, to a closed position wherein fluid flow between the flow passage and the valve chamber is obstructed thereby; and

b) using the pilot port to selectively apply a pilot pressure from the ventilator to the diaphragm in a manner facilitating the movement thereof to the closed position.

12. The method of claim **11** wherein step (a) comprises configuring the housing to include a pressure sensing port which fluidly communicates with the flow passage, and step (b) comprises sensing pressure within the flow passage through the use of the pressure sensing port to facilitate at least one of achieving and monitoring a therapeutic pressure level therein.

13. The method of claim **11** wherein step (b) further comprises initially supplying no pressurized, breathable gas from the ventilator to the patient via the direct nasal interface mask, and initially supplying no pilot pressure from the ventilator to the diaphragm.

14. The method of claim 13 further comprising the step of:

c) initiating the delivery of the pressurized, breathable gas from the ventilator to the patient at a prescribed therapeutic pressure level upon an occurrence of a predetermined event.

15. The method of claim 14 wherein the predetermined event of step (c) is at least one of:

(i) an elapse of a set time interval;

(ii) a detection of a patient breathing pattern indicative of an airway obstruction in the patient; and

(iii) a detection of a patient breathing pattern indicative of the patient falling asleep.

16. The method of claim 13 further comprising the steps of:

c) initiating the delivery of the pressurized, breathable gas from the ventilator to the direct nasal interface mask through the use of tubing having an inner diameter in the range of from about 1 mm to about 9 mm; and

d) delivering the pressurized, breathable gas from the ventilator to the direct nasal interface mask through the tubing at a delivery pressure level which exceeds a prescribed therapeutic pressure level for the delivery of the pressurized, breathable gas from the direct nasal interface mask to the patient.

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